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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/881,080      | 06/12/2001  | Terry Guinan         | P936 US             | 8025             |

7590 04/20/2004  
IP Legal  
Medtronic AVE, Inc.  
3576 Unocal Place  
Santa Rosa, CA 95403

EXAMINER

ODLAND, KATHRYN P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3743

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |                               |
|------------------------------|-------------------------------|-------------------------------|
| <b>Office Action Summary</b> | Application No.<br>09/881,080 | Applicant(s)<br>GUINAN ET AL. |
|                              | Examiner<br>Kathryn Odland    | Art Unit<br>3743              |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.  
     4a) Of the above claim(s) 6-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☒ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 November 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>29 December 2003</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment & Election***

This is a response to the amendment dated December 29, 2003 and the election dated March 22, 2004. Claims 1-5 are under consideration.

### ***Election/Restrictions***

1. Claims 6-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the paper dated March 22, 2004.

### ***Response to Arguments***

2. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

### ***Drawings***

3. The drawings are objected to because the helical slits are not shown in Figure 5 of the formal drawings. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

4. Claims 2 and 3 are objected to because of the following informalities: it is improper to use chemical product names in the claims when the specification does not define their chemical structure. Thus, HDPE, Pebax 6333, Peaxar Resin, and Pebax 7033 are improper. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1 and 3-5 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Duchamp in US 2002/0082549.

Regarding claim 1, Duchamp discloses a catheter assembly (generally at 10 and associated components) having an elongated tubular member (such as 13) having a proximal end and a distal end; a balloon (22) positioned at the distal end of the tubular member; an inflation lumen (84) extending through the elongated tubular member for providing inflation fluid for the balloon; a guidewire tubular member (71 and 80) extending from a position proximal the balloon through the balloon formed of a first material (71) having a first flexibility bonded to a distal segment formed of a second material (80) different from the first material and having a second flexibility; and a bond joining the balloon distal end to the proximal segment and the distal segment, as recited on pages 2 and 3 and seen in figures 1-6, with emphasis on sections [0026], [0027], and [0036]-[0044].

Regarding claim 3, Duchamp discloses that as applied to claim 1, as well as, a second material that is Pebax, as recited on page 3. It is noted that it is improper to include Pebax 7033 in the claim.

Regarding claim 4, Duchamp discloses that as applied to claim 1, as well as, an exit port proximal of a proximal end of the balloon, wherein the exit port provides access to the guidewire, as seen in figures 1-6.

Regarding claim 5, Duchamp discloses that as applied to claim 1, as well as, a second flexibility that is greater than the first flexibility, as recited on page 3.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duchamp in US 2002/0082549.

Regarding claim 2, Duchamp discloses that as applied to claim 1.

However, Duchamp does not explicitly recite a first material that is a trilayer. On the other hand, Duchamp discloses that the first layer can be a combination of materials similar to that claimed. Thus, a trilayer is within the scope of that claimed and it would be obvious to one with ordinary skill in the art. Moreover, it

is improper to claim Peaxar Resin and Pebax 6333 since their compositions are not disclosed in the specification.

***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

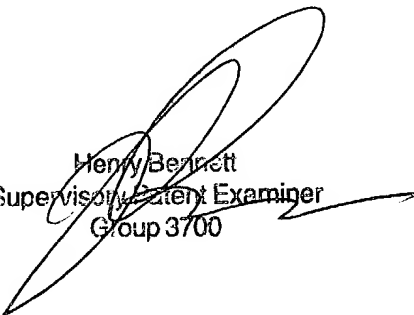
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO

  
Henry Bennett  
Supervisory Patent Examiner  
Group 3700